AMENDED PATENT LINKAGE REGULATIONS AND PATENT TERM EXTENSION NOW IN FORCE

By Urszula Wojtyra, Nancy Pei and Daphne Lainson

On September 7, 2017, the Government of Canada published final pharmaceutical regulations flowing from CETA. The new regulations, together with amendments to the Patent Act, came in to force on September 21, 2017.

These regulations herald a significant change to the landscape and environment in Canada for pharmaceutical companies, with long lasting impact to innovators in terms of exclusivity and drug product life-cycle management.

This scheme is now much closer to the US Hatch-Waxman scheme, but with key remaining differences. To view a comparison chart, *click here*.

PMNOC Regulations amendments

The amended regulations immediately apply to all submissions for which a notice of allegation is served on or after September 21, 2017. Any notice of allegation served before that date will be governed by the previous regulations.

The amendments to the regulations are accompanied by a regulatory impact analysis statement ("RIAS") outlining the background and objectives and describing the changes. The objectives are stated to include:

- replacing summary proceedings with a full right of action;
- providing equivalent and effective rights of appeal to all litigants; and
- ending dual litigation.

According to the "precis" published with the Order in Council promulgating the amended regulations, the regulations were amended to:

1. resolve a number of problems by replacing summary prohibition proceedings with full actions to determine patent validity and infringement;
2. expand the scope of the regulations to cover relevant certificates of supplementary protection, by providing an additional period of protection from new patented pharmaceutical products;
3. expedite proceedings by introducing a limited number of procedural rules, while still leaving the Court broad discretion to manage proceedings;
4. address concerns about how damages arising from delayed generic market entry are currently assessed; and
5. remove barriers that may prevent innovators and generics from litigating certain patents outside the regulations prior to generic market entry

Key specific amendments in the new scheme include:

- **New right of action for a declaration of infringement** following receipt of notice of allegation extending to all claims of listed patents. A claim for infringement of an unaddressed patent (including an unlisted patent) may also be brought outside the Regulations any time after receipt of a notice of allegation provided infringement could result from the making, constructing, using or selling of the drug in accordance with the submission

- **Sole opportunity to litigate listed patents:** a first person cannot bring an action outside the regulations unless it did not have a reasonable basis for bringing the action within the 45-day deadline
- **No explicit end date for section 8 damages period:** a first person can however renounce application of the 24-month stay, precluding any s. 8 liability
- **Certificates of supplementary protection ("CSPs") can be listed on the Patent Register** [see below]

CSP Regulations

The *CSP Regulations*, together with amendments to the *Patent Act*, are intended to compensate innovators for lost patent term due to regulatory delays. The regime allows for protection to take effect at the end of the term of the relevant patent which will be calculated by subtracting five years from the period beginning on the filing date of the application for the patent and ending on the day on which the authorization for sale is issued, for a maximum of **two years.**

Key provisions of the *CSP Regulations* include:

- **Prior Approvals and excluded variations:** a CSP is only available where no other CSP has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, which is defined to exclude prescribed variations (for example, esters, non-covalent derivatives, enantiomers, solvates, polymorphs, post-translational modifications).
- **Eligible patents:** the patent must be in force and must include at least one claim directed at the same medicinal ingredient or combination; use of the same medicinal ingredient or combination; or the same medicinal ingredient, or combination, as produced by a defined process (product-by-process). Pure process patents and patents claiming formulations are therefore excluded.
- **CSP application must be timely filed:** there is a 120-day deadline for applying for a CSP from the date of issuance of the marketing authorization (NOC) if the patent has issued by that date or from the date of patent issuance, if the patent issues after the NOC date.
- **The application for marketing authorization must be timely filed relative to first foreign applications:** The deadline for filing the regulatory submission in Canada is 24 months, if the application for a CSP is filed no later than September 21, 2018, and 12 months, in any other case.

Health Canada has published a guidance document outlining the application process under the CSP Regulations, and a notice regarding the application of the PMNOC Regulations amendments. The Federal Court has also published a practice notice regarding actions brought under the PMNOC Regulations amendments.

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- The new linkage litigation landscape
- Availability of supplementary protection, and relationship to patent linkage
- Proposed regulatory change and its impact on patenting

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